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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,425	10/30/2001	Bolten L. Suzanne	3196/00 US	2066
26648	7590	04/06/2004	EXAMINER	
PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,425	SUZANNE ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 3-9, 30-34, 36-45, 50-56 and 59-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10-29, 35, 46-49 and 57 is/are rejected.
- 7) ☒ Claim(s) 2 and 58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group I, claims 1-2, 10-29, 35, 46-49 and 57-58 in the paper filed 3/15/04 is acknowledged. The traversal is on the ground(s) that Group VIII is drawn to the use of the host cell to produce an enzyme which is involved with a treatment process, and since it is the product of the reaction in claim 61 which is involved with the treatment process, "the method of claim 61 is not patentably distinct from the enzyme of claim 1, because the manufacture of the medicament occurs through the same mechanistic pathway and said mechanistic pathway is not part of the treatment process, but rather a means of creating a treatment". They also traverse on the grounds that since there are overlapping classes and subclasses in groups I-VIII, the examiner "will search each of these class/subclass combinations covering multiple inventions" and that the examination of all of these groups therefore presents no undue burden to the examiner. This is not found persuasive because claim 61 is involved with the use of host cells (not an enzyme as stated) to produce a medicament for 4 different treatment methods. The examination of this claim involves whether there is enablement in the specification for treating these different conditions and also involves a different search. As to the overlapping classes and subclasses in groups I-VIII, the classified patent literature is only one of the areas examined in patent examination. There are also the written description and/or enablement issues under 35 USC § 112 first paragraph and all of the available prior art other than the classified patent literature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-9, 30-34, 36-45, 50-56 and 59-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 3/15/04.

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Claims 46, 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is confusing in the recitation of "any of claim 35". There is only one claim 35.

Claim 49 is indefinite in the recitation of "said subcellular membrane fractions microsomes" in step d). There is no antecedent basis for this term.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10-29, 35, 46-49 and 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO:1 or that hybridize under high stringency conditions to SEQ ID NO:1, does not reasonably provide enablement for claims of the scope of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches that the nucleic acid of SEQ ID NO:1 is isolated from *Aspergillus ochraceus* and that this nucleic acid encodes an 11 alpha hydroxylase that is active on androstenedione. It does not teach the isolation of any and all nucleic acids encoding an *Aspergillus ochraceus* 11 alpha hydroxylase. Furthermore it does not teach that the hydroxylase is

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active on all of the substrates of claims 10-15, 18 and 35 but only against androstenedione (see page 67, last paragraph through the paragraph spanning page 68-69). The examiner cannot readily determine which of the substrates in claims 10, 11, 15, 18 and 35 correspond to androstenedione and applicants assistance in determining this is requested, citing either the specification and/or prior art. Essentially any nucleic acid will hybridize in the stringency is low enough so that only nucleic acid that hybridize under high stringency conditions are enabled by the specification.

One of ordinary skill in the art would not be taught by the instant specification to make and/or use nucleic acids of the scope of the instant claims without undue experimentation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 57 is rejected under 35 U.S.C. 102(b) as being anticipated by either of Tudzynski, et al. (U) or Kennedy, et al. (V). As discussed *supra*, essentially any nucleic acid will hybridize to another if the stringency conditions are low enough. It is maintained that the nucleic acids of the instant reference will hybridize under low stringency conditions to the nucleic acid of claim 2, absent very convincing proof to the contrary.

Claims 2 and 58 are objected to as being dependent upon a rejected base claim.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
April 2, 2004